Journal of Pharmaceutical and Biological Research

Journal Home Page: www.pharmaresearchlibrary.com/jpbr

Research Article

A Study on Regulatory Guidelines for Product Development in Clinical Trial Research Studies in India, USA, AUSTRALIA

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ABSTRACT

Drug discovery has a long history and dates back to the early days of human civilization. In those ancient times, treatments were often discovered by chance or resulted from observation of nature, typically but not exclusively, using ingredients extracted from plants/animals, and not just used for physical remedy but also for spiritual healing. The study aims to assess the regulatory guidelines for product development in clinical trial research studies in India, USA, and Australia. Drug development research, in particular, is long and arduous and bringing a single new drug costs on an average USD 1.78 billion and takes approximately 13.5 years from discovery to the market. Drug development research is primarily funded by the pharmaceutical industry including the process of human testing (Phase I-IV studies). These studies (called clinical trials or regulatory studies) are conducted with the academician as the principal investigator largely in academic centres. The pharmaceutical industry funds or 'sponsors' the studies and ensures compliance with the country's regulatory requirements. It is the role of public regulatory authorities to ensure that pharmaceutical companies comply with regulations. There are legislations that require drugs to be developed, tested, trailed, and manufactured in accordance to the guidelines so that they are safe and patient's well - being is protected. The government agencies should identify and promotes health campaigns regarding drug information services.

Keywords: Product development, Drug development research, Regulatory guidelines, pharmaceutical companies, Regulations.

ARTICLE INFO

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Journal QR-Code

ARTICLE HISTORY: Received 15 April 2023, **Accepted** 31 May 2023, **Available Online** 22 July 2023

Citation: *K. Sunil Kumar, et al. A Study on Regulatory Guidelines for Product Development in Clinical Trial Research Studies in India, USA, AUSTRALIA. J. Pharm. Bio. Res., 2023, 11(1): 05-14.*

CONTENTS

1. Introduction

Drug discovery has a long history and dates back to the early days of human civilization. In those ancient times, treatments were often discovered by chance or resulted from observation of nature, typically but not exclusively, using ingredients extracted from plants/animals, and not just used for physical remedy but also for spiritual healing. Modern drug discovery research started to being performed around the early 1900s. Nowadays, the development of a new medicine usually starts when basic research, often performed in academia, identifies a macromolecule (i.e., a molecule with a large molecular weight like genes/proteins), or a dysfunctional signaling pathway or a molecular mechanism apparently linked to a disease condition (pre-discovery stage). In general, at this stage, research teams attempt to identify the so-called therapeutic targets (often a protein) that are linked to the disease state. To be nominated therapeutic target, scientists will also have to find therapeutic agents that modify the function of the perturbed target and restore health or alleviate symptoms. Finding the right target is however extremely challenging. Further, drugs are efficient in humans because of specific actions on the intended therapeutic target but also due to interactions with other, unintended (often unknown) targets! The process continues with the search of therapeutic agents followed by a preclinical phase, during which potential drugs are tested in a battery of animal models, to demonstrate safety and select drug candidates (novel strategies to avoid animal testing are being developed, see below). Clinical studies in humans can then get started to establish safety and efficacy of the drugs in patients with the highest benefit-to-risk ratio[1-5]. The studies are then submitted to regulatory agencies, which review the documents and decide about market approval. If the review is positive, the drug can then be released to the market and be administrated to patients. Once a drug has been approved, investigations continue to monitor putative side effects that could be caused, over time, by the new treatment[1-6]. This last step is often referred to as pharmacovigilance studies (or real-world evidence), generally dubbed “phase 4” clinical trial. The entire drug discovery and development process involves many disciplines, years of efforts and is very expensive. It also implies the generation and use of vast amount of data usually obtained via different types of high-throughput technologies. Many of these experiments and the analysis of the results can be automated via computer-assisted methods to speed-up some steps of the process, gain knowledge and reduce mistakes.

2. Methodology

India

Indian consumers are being constantly exposed to advertisements for prescription as well as non-prescription via television, internet, social media & other forms of media. Knowledge about pharmaceuticals products obtained from various sources that are followed by the literate and illiterate person without consulting a pharmacist or physician which leads to self-medication practice. Celebrities and other famous spokespersons hire by the pharmaceutical advertiser for promotional products. Currently in India, there is no focal constitutional agency for uniform regulations in the advertising business. Pharmaceutical advertisements and promotion activities are regulated under the Drug and Cosmetic Act (1940), DMR (Objectionable Advertisements) Act, 1954 and CP Act, 2019. The goal of the DMR Act was to restricted claims of witches, faith healers and voodoo experts or other professionals from influencing individuals. In India advertising allowed only for OTC and Ayurveda drugs. however, it does not legally recognize a list of OTC drugs. Ayurveda products advertisement are common in India because pre-approval for advertisement is not needed. No regulation specifies the minimum essential information requirements for an advertisement. ASCI is a non-statutory body that completely directed and controlled the Indian advertising market[6-9].

Advertising approval process in the USA

Promotional and labeling approval is mandatory for prescription products in the USA. Surveillance of pharmaceutical advertising is important for protecting consumers and better information for health care professionals. OPDP reviews prescription drug advertising and labeling to ensure the information is correct and not deceptive or misleading. Agencies should back up their advertising claims with verified solid evidence. The Bad Ad Program is regulated by the OPDP in the CDRH by FDA in 2010. The main goal of the Bad ad Program is to increase awareness about false and misleading advertising to health care professionals and reports about advertising and labeling materials.

Australia

In Australia pharmaceutical products like patient diagnostics, medical devices or drugs described as “Therapeutic Goods” which means products for human use for healthcare purposes. Pharmaceutical advertising devotedly under the regulatory framework in Australia. Therapeutics advertising on any media platform about all kinds of products and services (Prescription and non-prescription) or packaging which creates a false impression on consumers is illegal as per the Australian laws. Therapeutic Goods Act,1989 is administered by the TGA which has the legal power to pre-market, post-market monitoring and withdraw advertisements approval. Section 42DL of TG Act,1989 prohibits illegal, biological and prescription product advertisements in Australian territory.

Advertising approval process in Australia

Advertising of medicinal products allowed for medical device, complementary and non-prescription medicines in digital and print media. But prior approval required for advertising of complementary and non-prescription medicines was mandatory in Australia before July 2020.

Exclusive data is required for prior approval of therapeutics products in different forms of media. Prior approval by TGA is an essential form of advertising of therapeutics goods use in serious defects, diseases and conditions which is known as restricted representation. Advertisement approval is a combination of self-regulation and national legislation. Two associations are responsible for advertisement approval of healthcare products in Australia are CHC: Complementary Healthcare Council, ASMI: Australian Self-Medication Industry. Off-label promotion and advertising activities of therapeutic goods and services are restricted in the ACT.

3. Results and Discussion

Drug development research, in particular, is long and arduous and bringing a single new drug costs on an average USD 1.78 billion and takes approximately 13.5 years from discovery to the market. Drug development research is primarily funded by the pharmaceutical industry including the process of human testing (Phase I-IV studies). These studies (called clinical trials or regulatory studies) are conducted with the academician as the principal investigator largely in academic centres. The pharmaceutical industry funds or 'sponsors' the studies and ensures compliance with the country's regulatory requirements. Academicians, however, also carry out their own research and these studies are called as 'Investigator initiated studies' (IISs). Here, the academician raises funds for the study through his efforts from various sources including possibly the pharmaceutical industry. In these IISs, he dons the dual mantle of an investigator and 'sponsor' and thus directly becomes responsible for ensuring regulatory compliance.

Anaesthesia as a speciality straddles several diverse disciplines that include various branches of surgery and medicine as well as critical care and pain management among others. The past three decades have also seen remarkable advances in the field of anaesthesia, some of which include pulse oximetry, end-tidal gas monitoring, introduction of propofol and the laryngeal mask airway. Anaesthesiologists are uniquely positioned to carry out translational research given the data-rich environment in which they practice and this research can be used successfully to guide evidence-based practice of the discipline as also public health policy Regardless of the nature of the research (Regulatory Clinical Trials or IISs), knowledge of the regulatory requirements is an essential imperative for researchers. The present article details these requirements giving their historical evolution, the key bodies in India that govern or oversee research along with 'must know' and 'good to know' for the conduct of clinical trials in the country[10-11].

THE NATIONAL REGULATORY BODY – THE CENTRAL DRUGS STANDARD CONTROL ORGANISATION AND THE DRUGS CONTROLLER GENERAL OF INDIA

The Central Drugs Standard Control Organization (CDSCO) is the National Regulatory Authority in India. Its equivalent counterparts elsewhere include the United States Food and Drug Administration (US FDA), Health Canada and the European Medicines Agency. CDSCO is an arm of the Ministry of Health and Family Welfare, Government of India. Its mission is to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

Drug Approval Regulatory & Process In The United States

The United States represents the largest continental pharma market worldwide and holds around 45% global market. The pharmaceutical market in the United States was expected to increase from $354bn in 2015 to $497bn by 2020. The FDA is the main regulatory body that handles drug approval in the United States. Though markets like China and India have shown a massive leap in the pharma market, the United States and Europe are still the key players in the pharmaceutical industry. The United States has the world's most stringent standards for approving drugs, and drug approval standards are considered the benchmark by many regulators worldwide[12-14].

The Food and Drug Administration (FDA) is responsible for protecting and promoting public health. The Center for Drug Evaluation and Research (CDER) is a division of the U.S. Food and Drug Administration (FDA) that monitors most drugs as defined in the Food, Drug, and Cosmetic Act. FDA approval process begins only after the submission of the Investigational New Drug (IND) application.

Who can submit IND, NDA & NDA 505(b)(2) drug applications?

- The applicant, or the applicant's attorney, agent, or authorized official must sign the NDA.
- If the person signing the NDA does not reside or conduct business within the United States, the NDA is required to contain the name and address of, and be countersigned by, an attorney, agent, or an authorized official who resides or maintains a place of business within the United States.

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The approval process for Investigational New Drug (IND)

If the results prove safe in the preclinical trials, the sponsor can submit an Investigational New Drug (IND) application with the FDA to start clinical trials in humans. The sponsor is responsible for the submission of the IND application. A Pre-IND assessment can be organized with the FDA to deliberate multiple issues such as:

- The design of animal research, which is required to lend support to clinical studies.
- The intended protocol for conducting the clinical trial.
- The chemistry, manufacturing, and control of the investigational drug.

Drug approval process in Australia

The TGA registration process for prescription medicine applications, that need to be supported by nonclinical, clinical and/or bioequivalence data (category 1 and category 2). This regulatory process is designed to improve the efficiency and timeliness of the registration of prescription medicines without compromising the scientific rigour of the evaluation process, thus ensuring the maintenance of appropriate standards of quality, safety, and efficacy. This document describes this process and outlines the relevant regulatory requirements.

The key elements of this process are: management by milestones

An improved quality of dossiers prepared in accordance with common technical document (CTD) format and other TGA regulatory requirements. a pre-submission planning phase where applicants lodge details of a proposed application at least 2¼ months prior to lodgement of the dossier allowing the TGA to identify milestone dates and plan resource requirements (this is not required for submissions lodged in eCTD format if the sponsor selects the PPF-only option) a submission phase where the applicant must lodge a complete dossier, there being no opportunity to deliver new data after the submission date except as required by the *Therapeutic Goods Act 1989*-external site (the Act) requests for information under section 31 of the Act are consolidated and issued at the end of the initial evaluation phase. Legislative instruments made under section 9D and section 23 of the Act support this process. These instruments provide the legislative basis for the documents that specify the regulatory requirements for applications lodged under this process[15-17].

Regulatory and supporting documents

- Category 1 and 2 applications for new registrations are made under section 23 of the Act. Section 23 requires that applications are made in a form approved by the Secretary. The currently approved form is the CTD format.
- Category 1 and 2 requests to vary the entry in the Australian Register of Therapeutic Goods (ARTG) of registered therapeutic goods are made under section 9D of the Act. Section 9D requires that applications are made in a manner approved by the Secretary. The currently approved manner is the CTD format.
- The CTD format is described in the following documents:
- CTD Module 1: Administrative information and prescribing information for Australia
- ICH M4Q Common technical document for the registration of pharmaceuticals for human use - Quality (CPMP/ICH/2887/99 Rev 1 Quality)
- ICH M4S Common technical document for the registration of pharmaceuticals for human use - Safety (CPMP/ICH/2997/99 Rev 1 Safety)
- ICH M4E Common technical document for the registration of pharmaceuticals for human use - Efficacy (CPMP/ICH/2887/99 Rev 1 Efficacy).
- For category 1 and 2 applications, other than applications solely for an additional trade name, the section 23 and section 9D instruments specify applications must comply with the following regulatory documents:
- Mandatory requirements for an effective application
- Pre-submission planning form
- Prescription medicines (PREMIER) electronic lodgement facility (for applications to register a new chemical entity, new fixed combination, similar biological medicinal product or a new generic medicine) the form Application for the registration, or to vary the conditions of registration, of prescription medicines (all other applications).
- In addition to the documents specified by the section 9D and section 23 instruments, the TGA has produced other documents which provide further assistance for applicants who are lodging a PPF or dossier. These include:
- Prescription medicine registration process (this document)
- Information for applicants completing a pre-submission planning form
- Electronic format requirements for industry for providing regulatory information: Non eCTD electronic submissions (NeeS) for human medicinal products

Application

- Application refers to the regulatory activity required in respect of a product (a specific set of formulations, strengths and presentations) as requested by the applicant of the product.
- It is the specific set of information on the product submitted for review.

Drug approval process in Australia

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Pre-submission phase

- Under the registration process, applicants provide the TGA with planning data in the Pre-submission planning form (PPF) at the pre-submission phase. Planning data include general submission information as well as information about the proposed application type and details of the quality, nonclinical and clinical evidence that will be provided in the dossier. The PPF provides the TGA with the necessary information for effective resource planning.
- If the TGA considers a PPF complete and acceptable, the applicant will receive a Planning letter that provides key dates for the phases and milestones of the regulatory process for the application.
- Submission phase
- Applicants provide a dossier for evaluation at the submission phase. Applicants must ensure applications meet TGA regulatory requirements for format and content or the application will be considered 'not effective' and will not be accepted for evaluation. There will be no requests for information or documents under section 31 of the Act at the submission phase to address deficiencies in applications that do not meet TGA requirements.

- Applications must be received by the date noted in the Planning letter to allow the TGA to complete the necessary administrative activities by the end of the same month.
- At the end of the submission phase, the TGA will send the applicant a Notification letter advising that the application has either:
- Priority review designated applications
- TGA now has a formal Priority review pathway for faster assessment of vital and life-saving prescription medicines for which a complete data dossier is available. The target timeframe of 150 working days is up to three months shorter than the standard prescription medicines registration process. A valid Priority review designation must be held in order to access the Priority review pathway. More information on Priority review is available at:
- Priority review designation: A step-by-step guide for prescription medicines
- Priority review designation eligibility criteria: Including supporting documentation
- Priority review registration process[18]

Provisional approval pathway

- The TGA now has a formal Provisional approval pathway for the provisional registration of prescription medicines on the basis of preliminary clinical data, where there is the potential for a substantial benefit to Australian patients. A valid Provisional determination must be held in order to access this pathway.
- Information
- Applications must contain all the information and material required for purposes of section 9D or section 23 of the Act and the documentation presented at submission will be taken as the complete application.
- The applicant certifies in the PPF that the content of the complete dossier aligns with the information provided in the PPF and that the dossier, as received by the TGA, will be considered to be the full and complete dossier notwithstanding any further data requested by the TGA (including under section 31 of the Act) and/or new safety related data, which the applicant is obliged to bring to the TGA's attention. Applicants are strongly advised not to lodge a PPF before the full extent of the supporting data necessary for the application to be evaluated is known to be available.
- To assist applicants prepare a complete application, TGA has published numerous documents and guidelines on the preparation and submission of prescription medicine applications. Applicants of prescription medicine applications should refer regularly to the TGA web site for those guidelines and policies relating to a particular application type of interest. Where a relevant guideline is not met, an appropriate justification must be provided in the dossier.
- Once an applicant has submitted the dossier to TGA any data received by TGA without being requested by TGA will be considered 'unsolicited information.
- Data submitted after submission of the dossier must be accompanied by a covering letter which includes the submission number of the relevant application, the purpose of the correspondence and whether the information and material is 'solicited' or unsolicited.
- Solicited information
- TGA considers the following to be solicited information:
- Information and documents sent in response to the consolidated section 31 request following the first round assessment phase. The request will be sent on the date identified in the Notification letter allowing applicants time to conduct any necessary preparation activities.
- Responses to informal requests from TGA staff for information or documents (for minor issues and clarifications). These requests may occur throughout the evaluation process and are intended only to maintain efficiency in the evaluation process, not to rectify deficiencies in incomplete or poor quality applications.
- All solicited information in response to questions should be submitted in a question and answer format which is cross-referenced to replacement volumes where appropriate.
- Unsolicited information
- TGA will accept the following unsolicited information for evaluation:
- Safety data (see 2.5.3 for the definition of safety data). Applicants are obligated to inform the TGA as soon as new safety data becomes available.
- New/ renewed/ updated TGA manufacturing licences (for Australian manufacturing sites) and good manufacturing practice (GMP) clearances (for overseas sites) issued for those sites identified in the application.
- Revised trade names. An applicant may change, but not add, a trade name at any time prior to the end of the second round assessment phase.
- In the event that the TGA receives other unsolicited information from an applicant, the applicant should be aware that there is a likelihood that the TGA will not evaluate the data. Applicants must, therefore, ensure that their dossier contains the full data set that they wish the TGA to evaluate and that the mandatory

requirements (as applicable to the nature of the medicine and application type) are met.

- The TGA will work with applicants of medicines of critical importance to the Australian community in emergency situations to ensure this policy does not adversely affect the timely evaluation of such medicines. Applicants of such medicines are encouraged to discuss arrangements with the TGA at a pre-submission meeting and in any case, as early as possible.

Safety data

- For the purposes of the registration process, new safety data refers to information that might negatively influence the benefit-risk assessment of a medicinal product. Examples include but are not limited to:
- an increase in the rate of occurrence of an 'expected,' serious adverse drug reaction which is judged to be clinically important
- a significant hazard to the patient population, such as emergent lack of efficacy with a medicinal product used in treating a life-threatening disease, or a spate of unlisted reports of an uncommon or rare but serious adverse event a major safety finding from a newly completed animal study (such as an increased incidence of tumours in treated animals) pooled analyses of clinical studies that suggest significant dose or time dependent adverse effects that were neither apparent nor available at the time of lodging the application safety data associated with regulatory action in the event of, or to prevent risk to public health associated with use of the product in countries where it is already registered.

Safety data in this context do not include, for example:

- studies which only confirm information previously submitted to the TGA, including extension studies of submitted nonclinical or clinical studies (i.e. a, b and c above do not apply)
- studies or other data which support the use of the medicine in accordance with the proposed recommendations but which do not identify a new unexpected adverse drug event or an increased incidence of an expected adverse drug event
- Pharmaceutic data
- Nonclinical studies to justify proposed impurity limits.
- Planning and tracking of applications
- Regulatory phases
- The regulatory process for evaluation of prescription medicines consists of eight phases. Each phase has a milestone that must be completed before commencement of the following phase. This approach allows effective and transparent management of resources and timelines for all applications.

Submission planning

- Planning for the evaluation process occurs during the pre-submission phase where the application type, the product, the scope and scale of the application, and the date of proposed dossier lodgement are identified. The information provided in the PPF allows the TGA to identify the resources required, including the specific areas of expertise, to evaluate an application. This phase also allows for the identification of any circumstances that may require the standard timeframe to be altered. Applicants will be notified of any alterations to the target timeframes.
- Under the registration process, the TGA begins allocating resources for the evaluation phase when the PPF is lodged. These resources are based on the expected date of dossier lodgement. If a dossier does not arrive by the expected date, the TGA will reallocate the resources for that application and the applicant must re-commence the regulatory process from the beginning by lodging another PPF.

Submission tracking

- Once the PPF is lodged, the TGA will track the application through the regulatory process. Each phase of the regulatory process concludes with the completion of a milestone.
- At key points in the registration process TGA will notify the applicant of the evaluation plan milestone dates: an evaluation plan is included in the Planning letter at Milestone 1, the Notification letter at Milestone 2 and the Milestone 3 letter at Milestone 3. As target timeframes may change, applicants should always consult the most recent letter.
- To facilitate tracking, the TGA has implemented a single email address for the applicant through which formal correspondence will be coordinated. The TGA point of contact should be the PMAB Case Manager of the relevant clinical evaluation unit. Information on the areas of responsibility for the clinical units is included in Clinical evaluation sections for prescription medicines.

Pre-process activities

Pre-submission meetings

Applicants may wish to discuss scientific or procedural issues with the TGA in a pre-submission meeting prior to preparing a PPF or dossier. Such discussions should occur well in advance of PPF and dossier lodgement. The TGA strongly recommends that applicants organise a pre-submission meeting for complex applications. Meetings between TGA and applicants are conducted according to the processes described in the guideline Pre-submission

meetings with the TGA. Applicants will need to provide details in the PPF and the dossier (Module 1.8.1) of any meetings conducted with the TGA.

Availability of dossier

- The PPF requires applicants to identify a proposed dossier lodgement date. Applicants should not lodge a PPF until they are confident all the data necessary for the evaluation of the application will be ready for delivery on the proposed dossier lodgement date.

Pre-conditions

- Applicants may need to fulfil a number of pre-conditions before lodging a PPF. In some cases, evidence is required in the PPF that the approval process has commenced on related activities. These are described below.

Orphan drug applications

- For designated orphan drugs, the Secretary waives application and evaluation fees for the evaluation of a medicine for the purposes of registration. For fees to be waived, the applicant must apply for, and be granted by the TGA, orphan drug designation before lodging the PPF. Further information about making such a request can be found in:
- Applications for orphan drug designation.
- Discussions with the TGA regarding orphan drug applications should commence well before the pre-submission phase. Applications for orphan drug designation should be lodged with the TGA two to three months before the intended start of the pre-submission phase. If an applicant has not received approval for the designation but chooses to proceed with the application, they become liable for the relevant application and evaluation fees.

Literature-based submissions

- For applications using literature references as all or part of the supporting data set, the applicant must seek the TGA's agreement on the following before lodging the PPF:
- The search strategy employed
- The databases to be searched
- The criteria for determining which papers identified by the search results are to be included/excluded from the dossier.
- These requirements are necessary because the data provided in the dossier is dependent on the search strategy. Applicants should plan to discuss these issues with the TGA at least three months prior to the pre-submission phase. Further information on literature-based submissions is provided in Literature-based submissions.

Fixed combination applications

- For a new fixed combination product the applicant must justify, prior to lodging a PPF, the particular combination and the type and extent of data to be provided in the dossier. This is done by preparing and lodging with the TGA a 'justification for fixed combination'. This is a letter to the TGA that presents the case for the fixed combination, prepared according to the following EU guidelines that have been adopted in Australia:
- CHMP/EWP/240/95 Rev. 1 - Guideline on clinical development of fixed combination medicinal products
- EMEA/CHMP/SWP/258498/2005 - Guideline on the non-clinical development of fixed combinations of medicinal products
- If one or more of the component active ingredients of the fixed combination product is/are not registered, the justification must include the proposed dossier lodgement dates for the unregistered components and the fixed combination product.

Ingredients

- The TGA maintains databases of proprietary and non-proprietary ingredients which can be accessed from the TGA's eBS portal- external site. Where an applicant wishes to register a new product that contains a new ingredient (one that is not on the databases), the applicant must commence, before lodging the PPF, the process for approval of a new ingredient for inclusion on the relevant databases.
- Genetically modified organisms (GMOs)
- It is likely that approval from the Office of the Gene Technology Regulator (OGTR) is required for medicines that:
- contain GMO(s)
- Consist of GMO(s) are manufactured in Australia and are derived from GMOs.
- In such circumstances, applicants must apply to the OGTR- external site for a licence, an exemption, or a Notifiable Low Risk Dealing approval, before lodging the PPF. Any OGTR advice (for example, OGTR licence, acknowledgement of receipt of licence application, other record of consent) must be provided to the TGA with the PPF.
- Medicines scheduling
- Where a proposed application relies upon the rescheduling of an existing substance in the Poisons Standard, applicants must lodge an application for rescheduling prior to lodging the PPF:
- Application to Amend the Poisons Standard
- Concurrent applications
- Applications to amend any details for a product cannot be lodged until the product is listed on the ARTG. If an applicant wishes to make changes to a proposed product, the application cannot be

lodged until the registration process is finalized. The same requirement applies to a new chemical entity application currently under evaluation and a proposed new combination application (where the product contains the new chemical entity under evaluation).

- Where a product is already registered and there is an existing application (variation or registration) currently with the TGA, it is acceptable to lodge a concurrent application in certain circumstances, provided that the changes proposed in the applications are unrelated. The following table indicates when it may be appropriate to lodge concurrent applications.
- Registration process phases
- Click a link to find out more about each phase in the registration process. For a diagram of the registration process, see Appendix 2 - Registration process regulatory phases.
- Phase 1: Pre-submission
- Phase 2: Submission
- Phase 3: First round assessment
- Phase4: Consolidated section 31 request response
- Phase 5: Second round assessment
- Phase 6: Expert advisory review
- Phase 7: Decision
- Phase 8: Post-decision

4. Conclusion

The Drug approvals in the US, Europe & India are the most demanding in the world. The primary purpose of the rules governing medicinal products in US, Europe & India is to safeguard public health. It is the role of public regulatory authorities to ensure that pharmaceutical companies comply with regulations. There are legislations that require drugs to be developed, tested, trailed, and manufactured in accordance to the guidelines so that they are safe and patient's well - being is protected. Each country has its own specific rules and regulations to address the advertising of pharmaceutical products and services. Indian scenario of advertising regulation seems very bleak as compared to those of USA and Australia. In India, Urgent needs to establish central regulatory authority for control and supervision on the industry-specific advertisement. USA advertising legalizations are strict and different as compare to other developed countries due to DTCA. Promotional and labeling approval is mandatory for prescription products. However, DTCA is still controversial because it indirectly encourages irrational medical use and pricing pressure. The pharmaceutical advertising approval process was strict process for OTC and complementary products before 30th June 2020 in Australia. CHC and ASMI have stopped reviewing the advertisement approval process. The government agencies should identify and promotes health campaigns regarding drug information services. Through mass media and advertisement, uncontrolled information about prescriptions or over the counter medications should with easy accessibility in range with clarity of quality in data under controlled surveillance. Policymakers should focus on online advertisement regulation for consumer privacy and security.

5. References

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